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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/082,685 | 02/25/2002 | Martin P. Redmon | 0701100e | 4621 |

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06/09/2003

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EXAMINER

TRAVERS, RUSSELL S

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,685

Applicant(s)

Redmon et al

Examiner

R.S. Travers J.D., Ph.D.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-60 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 41-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 41-44, 49-50 and 55-56, drawn to controlled release pharmaceutical compositions containing descarboethoxyloratadine in a lactose free carrier.

II. Claims 45, 49, 51, 55 and 57, drawn to controlled release pharmaceutical compositions containing descarboethoxyloratadine in a lactose free carrier, in combination with an analgesic or a decongestant.

III. Claims 46, 49, 52, 55 and 58, drawn to method for treating histamine mediated disorders by administering controlled release pharmaceutical compositions containing descarboethoxyloratadine in a lactose free carrier.

IV. Claims 47, 49, 53, 55, and 59, drawn to a method for treating diabetic retinopathy by administering a controlled release pharmaceutical compositions containing descarboethoxyloratadine in a lactose free carrier.

V. Claims 48, 49, 54, 55 and 60, drawn to symptomatic dermographism or dermatitis by administering a controlled release pharmaceutical compositions containing descarboethoxyloratadine in a lactose free carrier.

The above delineated inventions differ as compositions of matter and unrelated therapeutic methods; and are independent and patentably distinct each from the other. The grouped inventions patentably distinct, a reference which would anticipate, or

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make obvious, the inventions of groups I-V would not necessarily obviate or anticipate the inventions in the other group. The searches are not co-inclusive as indicated by the diverse nature of the subject matter, thus, would represent an undue burden on Examiner. One skilled in the art would readily practice the invention of one of the above groups without infringing and or practicing the invention of another group. The subject matter is unique and has acquired a separate status in the art and is fully capable of supporting separate patents. For the foregoing reasons restriction is proper for examination purposes.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Applicant is reminded that upon the cancellation of the claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if one or more of the currently named inventors is no longer an inventor if at least one claim remaining in the application. Any amendment of inventorship must be

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accompanied by a diligently filed petition under 37 C.F.R. 1.48 (b) and by the fee required under 37 C.F.R. 1.17 (h).

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



Russell Travers
Primary Examiner
Art Unit 1617